UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/470,874	12/22/1999	MARC MEHRZAD JALISI	ACS-58267 (1700X)	6721

24201 7590 06/30/2005

FULWIDER PATTON LEE & UTECHT, LLP
HOWARD HUGHES CENTER
6060 CENTER DRIVE
TENTH FLOOR
LOS ANGELES, CA 90045

EXAMINER	
HAN, MARK K	

ART UNIT	PAPER NUMBER
3763	

DATE MAILED: 06/30/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/470,874	JALISI ET AL.	
	Examiner	Art Unit	
	Mark K. Han	3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 February 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *22 December 1999* is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 04 February 2005 has been entered.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 1-10 and 13-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,636,641 to Fariabi in view of U.S. Patent No. 5,720,300 to Fagan.

Fariabi teaches a heat-treated elongate member/guide wire comprising a composite elongate core, the composite elongate core formed in part of an aged hardened material and in part of a superelastic material, a flexible body disposed at a distal end of the distal section, wherein the aged hardened material and superelastic material extend from the proximal section to at least substantially in a radial direction underneath the flexible body, the distal section having a proximal portion and a tapered distal portion, the aged hardened material comprising of at least two materials selected from the group consisting of nickel, cobalt, molybdenum,

chromium, tungsten, and iron (Column 3, Lines 49-51, 64-65). Fariabi does not teach that the elongate core is formed in part of a precipitation hardened material and in part of a superelastic material. Fagan teaches of an elongate core formed of a precipitation hardened material (Column 4, Lines 54-58). Fagan discloses that in order to avoid kinking of a guidewire it is necessary to have a desirable material that has equal compressive and tensile yield stresses. Such a desirable material, teaches Fagan, is made of a precipitation hardened material (Column 4, Lines 41-58). It would be obvious to one with ordinary skill in the art to use the teachings of Fagan to modify the invention of Fariabi to create a heat-treated elongate member formed at least in part of a composite elongate core, the composite elongate core formed in part of a precipitation hardened material and in part of a superelastic material, in order to create the necessary stiffness and push provided by the precipitation hardened material of the elongate core member and the desirable flexibility provided by the superelastic material of the elongate core member (Column 5, Lines 65-67, Column 6, Lines 1-10).

Fariabi discloses a high strength alloy containing cobalt, nickel, and chromium and particularly to a composite product having a portion formed of the high strength cobalt-nickel-chromium alloy and a portion formed of pseudoelastic alloy such as NiTi alloy (Column 2, lines 16-19). Fariabi further discloses that one embodiment of the invention is an elongated member formed at least in part, of alloy comprising about 28%-65% cobalt, about 2%-40% nickel, about 5%-35% chromium an up to about 12% molybdenum. Other alloying components include up to 20% tungsten, 20% iron and 3% manganese. The alloy may also contain inconsequential amounts of other alloying constituents, as well as impurities, typically less than 0.5% each (Column 2, lines 21-30). Fariabi further states that in another embodiment of the invention, the

cobalt-nickel-chromium alloy is formed into a composite structure with a NiTi alloy (Column 2, lines 51-53).

In Figure 1, Fariabi shows the distal section (17) of the core member (11), which is disposed primarily within the coil (14), and is tapered to sequentially smaller diameters to provide gradually increasing flexibility along the length of the distal portion of the guidewire (10). Figure 2 depicts a guidewire (30) with a construction wherein the tapered distal section (31) of the core member (32) extends to the plug (33) which connects the distal end of the core member to the distal end of the helical coil (34) disposed about the distal section of the core member. The proximal section (35) of the core member (32) is of composite construction with a sheath (36) of high strength Co-Ni-Cr alloy and an inner member (37) of a pseudoelastic NiTi alloy. The high strength sheath (36) is removed from the core member to form the tapered distal section (31) to increase the flexibility of the distal section of the guidewire (30).

With regard to claims 2-7, 9, and 10, Fariabi does not teach a composite elongate core having a modulus of elasticity of at least 9,000,000 psi, 12,000,000 psi and 15,000,000 psi and an ultimate tensile strength of at least 150 ksi, 180 ksi, and 200 ksi. Fariabi also does not teach of a precipitation hardenable material such as precipitation hardenable stainless steel and chromium-nickel based single stage martensitic precipitation hardenable stainless steel. Fagan teaches an elongate member (52,56) formed at least in part of a composite elongate core (50) formed at least in pad of a precipitation hardened material such as an alloy composed of nickel, cobalt, molybdenum, and chromium (MP35N and Eligiloy) having a small amount of iron (Column 5, lines 2-4), 455PH stainless steel or stainless steel alloy 1 RK91. 455PH is known to be a chromium-nickel based single stage martensitic precipitation hardenable stainless steel

(Column 6, lines 1-4., Column 10, lines 36-59). Fagan teaches that these alloys are exemplary because when bent, they will remain elastic through a greater range of stresses than prior guidewires. Since tensile yield stress and compressive yield stress are substantially less disproportionate, compressive failure is delayed, thus enabling the wire to be bent in a sharper curve without permanent deformation (Column 5, Lines 18-59). It would be obvious to one with ordinary skill in the art to use the teachings of Fagan to modify the invention of Fariabi to create a better performing guidewire that will remain elastic through greater range of stresses. Fagan discloses in Column 10, lines 65-66, that the alloy can have a modulus of elasticity compared to that of type 304 stainless steel (approximately 28,000,000 to 29,000,000 psi.). In addition, the alloy can have a tensile strength as low as about 150 ksi, but preferably about 250 ksi. (Column 10, lines 63-66). Fagan teaches that the modulus of elasticity and the tensile strength depend on the degree to which it is desired to precipitation harden the alloy (Column 11, Lines 5-16) in order to create a guidewire with a smaller diameter without compromising performance. It would be obvious to one with ordinary skill in the art to use the teachings of Fagan to modify the invention of Fariabi in order to create a smaller diameter guidewire for better performance.

3. Claims 11 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fariabi in view of Fagan, in further view of Reiss (WO 98/22024). Fariabi and Fagan teach all of the claimed limitations except a precipitation hardenable stainless steel essentially nickel free and a precipitation hardenable stainless steel including less than about 1% nickel. Reiss discloses a guidewire (10) comprising an elongated core element (12) manufactured from a martensitic alloy that is heat-treated to render a fully hardened core throughout its cross sectional area (see Abstract). Reiss further discloses examples of temperature hardened, martensitic steel alloys

such as carbon, manganese, chromium, silicone, molybdenum, iron, and nickel. As can be seen from page 7, Table 11, line 9, the amount of nickel that can be used is negligible or in other words, essentially nickel-free or containing less than about 1% nickel. Reiss teaches nickel to be one of the hardened alloys used in guidewires having a hardened core having the characteristic of superior torsional control or torque transmission (Page 6, Lines 30-32 and Page 1, Lines 6-8). It would be obvious to one with ordinary skill in the art to use the teachings of Reiss to modify the invention of Fariabi and Fagan to create a guidewire that is essentially nickel-free or contains less than about 1% nickel in order for the guidewire to perform with superior torsional control or torque transmission.

Response to Arguments

4. Applicant's arguments filed 04 February 2005 have been fully considered but they are not persuasive.

Applicant attempts to distinguish the claimed invention over the prior art. However, the claim language "underneath the flexible body" still implies a position outside the flexible body. It is recommended that the term "within the flexible body" would more accurately define applicant's invention. Nevertheless, such an amendment would not distinguish the claimed invention over the prior art. Fariabi discusses that the construction of the guidewire has a outer sheath of Co-Ni-Cr alloy and an inner member formed of Ni-Ti. See col. 4, line 55 through col. 5, line 5. Fariabi specifically discusses that the composition of the distal section of the core member comprised of the outer sheath and the inner member does not change until the tapering within the sheath as referenced by numeral 17 in Figure 1. Such a teaching along with the

suggestions of Fagan would render the claims unpatentable. The rejection under 35 U.S.C. §103(a) is hereby maintained.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark K. Han whose telephone number is 571-272-4958. The examiner can normally be reached on Monday to Friday, 9 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

NICHOLAS D. LUCCHESI
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700

Mark K. Han
Patent Examiner
Art Unit 3763

mkh
June 27, 2005